Annex I

Scientific conclusions and grounds for the variation to the terms of the Marketing Authorisation(s)

Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for Ropinirole, the scientific conclusions are as follows:

In view of available data on spontaneous penile erection from post-marketing and literature cases (5 reports with positive rechallenge, including 4 cases with confirmed close temporal relationship and 2 cases with positive dechallenge), a causal relationship between ropinirole and spontaneous penile erection is at least a reasonable possibility and the product informations (PIs) of ropinirole containing products should be amended accordingly. These updates should be in both PIs for Parkinson's Disease (PD) and Restless Legs Syndrome (RLS), as the indications in these relevant cases was PD in 2 cases and RLS in 3 cases, and considering that these underlying diseases have no specific role in the occurrence of this ADR.

In view of available data on hiccups from post-marketing, clinical trials, and literature cases (2 reports with positive dechallenge and positive rechallenge, 12 other reports with positive dechallenge, including 7 cases with close temporal relationship, and 3 reports describing the occurrence of hiccups after ropinirole dose increase and the resolution of the event after dose decrease), a causal relationship between ropinirole and hiccups is at least a reasonable possibility and the PIs of ropinirole containing products should be amended accordingly. Given the potential mechanism of action and the reported cases, these updates are warranted for both indications (PD and RLS).

The CMDh agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the Marketing Authorisation(s)

On the basis of the scientific conclusions for Ropinirole the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing Ropinirole is unchanged subject to the proposed changes to the product information.

The CMDh reaches the position that the marketing authorisation(s) of products in the scope of this single PSUR assessment should be varied. To the extent that additional medicinal products containing Ropinirole are currently authorised in the EU or are subject to future authorisation procedures in the EU, the CMDh recommends that the concerned Member States and applicant/marketing authorisation holders take due consideration of this CMDh position.

Annex II

Amendments to the product information of the nationally authorised medicinal product(s)

Amendments to be included in the relevant sections of the Product Information (new text **<u>underlined and in bold</u>**, deleted text ~~strike through~~)

Summary of Product Characteristics

- Section 4.8

The following adverse reaction should be added under the **SOC Reproductive system and breast disorders** with a **frequency "not known"**:

<u>Spontaneous penile erection</u>

The following adverse reaction should be added under the **SOC Respiratory, thoracic and mediastinal disorders** with a **frequency "uncommon"**:

<u>Hiccups</u>

Package Leaflet

- Section 4

The following adverse reaction should be added with a **frequency "not known" (frequency cannot be estimated from the available data)**:

<u>Spontaneous penile erection</u>

The following adverse reaction should be added with a **frequency "uncommon: may affect up to 1 in 100 people"**:

<u>Hiccups</u>

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	February 2023 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	14 April 2023
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	8 June 2023